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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,672	04/02/2004	Fredrik Nicklasson	PC 27890A	9694

7590 12/15/2006

Evan J. Federman
Legal Division
Warner-Lambert Company, LLC
201 Tabor Road
Morris Plains, NJ 07950

EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,672	NICKLASSON ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 are pending in the application.

Election/Restrictions

Applicant's election of the species of soybean oil, sodium carbonate, sucralose, soy lecithin and sodium chloride in the reply filed on 10/27/06 is acknowledged. After careful reconsideration of the claimed invention, the restriction requirement has been removed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of copending Application No. US 11/561,650. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-46 'anticipate' Instant claims 1-11 in that they specifically teach sexual dysfunction compounds such as phosphodiesterase inhibitors (which are capable of intraoral uptake) in combination with cocoa powder , lipid ingredients such as cocoa butter and

oils, buffering agents such as carbonates and bicarbonates , sweeteners such as aspartame and emulsifiers such as lecithin. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of copending Application No. US 11/561,539. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-38 of '539 'anticipate' Instant claims 1-11 in that claims 1-38 of '539 teach a pharmaceutical composition containing nicotine (which is capable of intraoral uptake)and cocoa powder. The composition and methods of claims 1-38 of '539 further limit the nicotine/cocoa powder composition to include lipids such as cocoa butter and oils, buffering agents such as carbonates and bicarbonates, sweeteners such as aspartame and emulsifiers such as lecithin. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. US 10/816,672. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-16 of '673 'anticipate' Instant claims 1-11 in that they teach a pharmaceutical formulation

comprising tolterodine, cocoa powder, lipids such as cocoa butter and oil, buffering agents such as carbonates and bicarbonates, sweeteners such as aspartame and emulsifiers such as lecithin. Tolterodine is intraorally available as indicated by page 5 of the '673 specification. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-25 and 42-43 of copending Application No. US 10/271,186. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3-25 and 42-43 of '186 'anticipate' Instant claims 1-11 in that they specifically disclose a pharmaceutical composition containing nicotine (which is capable of intraoral uptake)and cocoa powder. The composition and methods of claims 1-38 of '539 further limit the nicotine/cocoa powder composition to include lipids such as cocoa butter and oils, buffering agents such as carbonates and bicarbonates, sweeteners such as aspartame and emulsifiers such as lecithin. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-6, 13-14, 21-

23, 25-31 and 47-53 of copending Application No. US10/634,159. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 3-6, 13-14, 21-23, 25-31 and 47-53 'anticipate' Instant claims 1-11 in that they specifically teach sexual dysfunction compounds such as phosphodiesterase inhibitors which are capable of intraoral uptake in combination with cocoa powder , lipid ingredients such as cocoa butter and oils, buffering agents such as carbonates and bicarbonates , sweeteners such as aspartame and emulsifiers such as lecithin. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Girsh (US 5,753,296).

Girsh (US 5,753,296) taught chocolate compositions containing hypoallergenic cocoa powder which advantageously included pharmaceutical agents for sublingual/mucosal delivery (see entire reference especially col.2, lines 61-67, col. 14, lines 3-52). In a specific embodiment, Girsh prepares a 'High phosphatidylcholine lecithin, sugar-free, chocolate flavored aspirin' in Example XXVII (col. 28) which comprised aspirin, hypoallergenic cocoa powder, lecithin, vanilla, cocoa butter and maltitol, formed into small units to be "...utilized as a pleasant tasting, high mucosal penetrating and oral absorbable delivery system which is maintained sublingually in the mouth until completely dissolved".

Girsh specifically explains that

> The inventive chocolate composition may be ultilized as a vehicle for delivery of oral medications to **mask drug flavor** and provide for enhanced drug uptake via the oral mucosa. For example, a dosage form may be prepared by coating a medicament with a chocolate coating according to the present invention, or by mixing the medicament in a liquid or powder form with the chocolate composition. A chewable tablet, e.g., aspirin tablet, may thus be formed. The drug may comprise any pharmaceutical suitable for oral delivery, in particular those drugs such as dihydroergotamine...which are difficult to deliver by the oral route on account of poor absorption... (see col. 14, lines 17-28 – emphisis added).

Although Girsh taught the use of *hypoallergenic* cocoa powder, it was cocoa powder none-the-less in the composition. Because Girsh taught every limitation of the claims, Girsh anticipates the claimed invention.

Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindberg (US 2003/0087937 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1- 24 of '937 specifically disclose a pharmaceutical composition containing nicotine (which is capable of intraoral uptake)and cocoa powder. The claims further limit the nicotine/cocoa powder composition to include lipids such as cocoa butter and oils, buffering agents such as carbonates and bicarbonates, sweeteners such as aspartame and emulsifiers such as lecithin thereby anticipating the claimed invention.

Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Lindberg et al. (US 2004/0126448 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lindberg et al. (US 2004/0126448 A1) teaches sexual dysfunction compounds such as phosphodiesterase inhibitors which are capable of intraoral uptake in combination with cocoa powder , lipid ingredients such as cocoa butter and oils, buffering agents such as carbonates and bicarbonates , sweeteners such as aspartame and emulsifiers such as lecithin. (see claims 1, 3-6, 13-14, 21-23, 25-31 and 47-53).

Claims 1-11 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. US 10/816,672. To reiterate, 1-16 of '673 'anticipate' Instant claims 1-11 in that they teach a pharmaceutical formulation comprising tolterodine, cocoa powder, lipids such as cocoa butter and oil, buffering agents such as carbonates and bicarbonates, sweeteners such as aspartame and

emulsifiers such as lecithin. Tolterodine is intraorally available as indicated by page 5 of the '673 specification.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Girsh (US 5,753,296) in view of Lapidus (US 4,937,076).

The teachings of Girsh were discussed *supra*. Girsh did not specifically teach wherein sodium chloride was added into Example XXVII nor did Girsh teach incorporation of a buffer such as sodium carbonate.

Lapidus (US 4,937,076) disclosed a chewable aspirin tablet containing, *inter alia*, chocolate, aspirin and calcium carbonate (see entire reference, especially Abstract and col's 3-4). Lapidus explained that the buffering component present in the aspirin-containing chewable tablet advantageously contained a buffer in order to reduce gastric

anomalies caused by the aspirin (see col. 1). Lapidus suggested the use of many suitable buffering components, including sodium carbonate (see Col. 3, line 59- col. 4, line 11.

One of ordinary skill in the art would have been motivated to add a buffer such as sodium carbonate to the chocolate-aspirin composition of Girsh in order to advantageously decrease the gastric complications brought about by aspirin consumption. Although Girsh does not specifically teach the addition of buffers to the chocolate-aspirin composition, the ordinary artisan would have had a reasonable expectation that the addition of sodium carbonate would have suitably buffered the aspirin in the composition which would consequently provide a medicament which was more easily tolerated by patients..

One of ordinary skill in the art would have been motivated to use sodium chloride in the Example XXVII of Girsh in order to impart additional flavor to the chocolate-aspirin containing composition. It was clear from Girsh that salt was used as a flavorant in the chocolate containing compositions (see Example XV); and it is also well known that salt is a flavoring agent. Therefore, one of ordinary skill in the art would have had a reasonable expectation that the addition of salt to the chocolate-aspirin composition of Girsh would have provided for a more flavorable product.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention because cocoa powder containing vehicles were known in the art for the preparations of sublingual/transmucosal delivery of active agents. It is clear from the prior art that substances such as lecithins, cocoa butter, oils such as soybean oil, sweeteners and flavoring agents are routinely added to confectionary-type carriers containing chocolate/cocoa powder and that these types of carriers enhanced introral uptake of pharmaceutical agents. The addition of known, conventional additives to the composition does not render the composition patentable, because as stated *supra*, these compounds were routinely used in chocolate containing compositions and do not appear to impart any unexpected results to the composition. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

November 29, 2006